

Office Action Summary

Application No.

10/517,843

Applicant(s)

SWORDS, GREG

Examiner

SUBA GANESAN

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 10/15/08
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/3/09, 8/5/08,8/25/08,10/22/08.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/5/2008 has been entered.

Election/Restrictions

Claims 12-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/22/2008.

Applicant's election with traverse of Group 1 in the reply filed on 12/22/08 is acknowledged. The traversal is on the ground(s) that there is no undue burden to search all of the claims. Applicant's traversal has been carefully considered, but fails to establish error in the propriety of the present requirement for restriction and election.

Though Applicant asserts that examination of all pending claims would not pose an undue burden on the Examiner, such is not an accurate assertion in light of the disparate nature of the presently claimed subject matter as noted in the Requirement for Restriction of 12/10/08.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the entirety of Applicant's claims would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§101,102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified. Therefore, it is obvious that a comprehensive search of the copious amounts of patent and non-patent literature for each of the patentably distinct inventions and their permutations presently claimed would necessarily place an undue burden on the Examiner.

Therefore, for the reasons above and those made of record in the Requirement for Restriction of 12/10/2008, the restriction requirement is deemed proper and is made FINAL.

Claims 12-21 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being to non-elected inventions, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

2. Applicant's arguments filed 8/25/2008 have been fully considered but they are not persuasive. Morgan discloses a solid barrier, since the term solid refers to nothing

more than not a liquid or gas. The polymer layer of Morgan is a barrier because it prevents cells from penetrating the layer.

3. With respect to Wellisz, the polyethylene layer is disclosed as being a lattice to promote tissue ingrowth.

Response to Amendment

4. The Declaration of Commercial Success under 37 CFR 1.132 filed 8/25/08 is insufficient to overcome the rejection of claims 1-11 and 22-25 based upon 35 USC 103 as set forth in the last Office action because: the declaration fails to provide a showing that other economic or commercial factors are not responsible for commercial success.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 7-8, 10-11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (U.S. Pat. No.: 5380328).

7. Morgan discloses a craniofacial implant comprising a porous thermoplastic resin (PTFE or HDPE) barrier and a titanium mesh. However, Morgan lacks the thermoplastic layer filling the interstices of the mesh. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the sandwich-type assembly of Morgan with an alternate processing means using heat and pressure to fill the interstices of the titanium mesh with the porous thermoplastic resin (PTFE or

HDPE), resulting in an improved adhesion between the layers to prevent layer separation and dislocation. Such methods are known in the art, and would have yielded predictable results.

8. Since the basic structural elements of the claims are met by Morgan (titanium mesh, porous thermoplastic resin barrier), it is understood that one of ordinary skill in the art would envision multiple means of assembling the components of Morgan together. These alternate assembly means are well within the design purview of an ordinary worker in the art, and would have occurred for a plurality of reasons, including: ease of manufacturing or preventing layer separation.

9. With respect to claims 7 and 8, the material of Morgan comprises HDPE. With respect to claims 10-11, Morgan discloses means for attaching to bone (for example col. 7 lines 1-11).

10. Claims 6, 9, 22-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (U.S. Pat. No.: 5380328) in view of Wellisz (U.S. Pat. No.: 5,743,913).

11. Morgan in explained supra, however, Morgan discloses the polymer layer having pore sizes of .2-3 microns such that the polymer layer prevents tissue cells from passing through for the purpose of protecting tissue regeneration at the defect site. Morgan does not disclose pores sized to allow tissue ingrowth. Wellisz teaches the use of polyethylene granules on a titanium bone implant for the purpose of acting as a lattice to promote tissue ingrowth and thus healing. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to have provided the bone-facing surface of the Morgan implant with a layer consisting of polyethylene granules as taught by Wellisz for the purpose of allowing bone ingrowth and thus healing and improved anchoring of the Morgan prosthesis. This combination would not destroy the Morgan reference, because the ingrowth layer is on the bone-facing surface and Morgan recognizes the need for bone regeneration (see abstract).

12. With respect to claims 22 and 23, Wellisz teaches the use of polyethylene granules in a layer. The combination rejection is based upon combining this layer with the titanium mesh and top barrier layer of Morgan. The barrier layer of Morgan is micro-porous, which is still porous, and Examiner considers the polyethylene lattice of Wellisz to be porous (inherently because it is a scaffold for tissue ingrowth). Thus the combination of Morgan and Wellisz comprises porous polyethylene matrix wherein all sides of the implant have porous surfaces. However, the combination, specifically Wellisz does not address the pore size required for tissue ingrowth. It would have been obvious to one of ordinary skill in the art to have provided a pore size of between 20 and 500 microns since such a porosity range would be suitable for allowing tissue ingrowth. It would have been obvious to try a range of porosities to discover the optimal range of pore size to allow tissue ingrowth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774